

PCT



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PATENT

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Albert Zorko Abram  
Serial No. : 09/719,662  
Filed : December 15, 2000  
For : MOUSSE COMPOSITION

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PP.  
1692

0502

CLAIM FOR PRIORITY UNDER 35 U.S.C. § 119

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Date of Deposit

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Attorney Name

19,498

PTO Registration No.

January 30, 2001

Date of Signature

Signature

Assistant Commissioner for Patents

Washington, D.C. 20231

Sir:

A claim for priority is hereby made under the provisions of 35 U.S.C. § 119 for the  
above-identified PCT application based upon Australian application No. PP 5831 filed September  
11, 1998, and International Application PCT/AU99/00735 filed September 8, 1999.

Respectfully submitted,

Ronald B. Hildreth

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09/719662

I, KAY WARD, TEAM LEADER EXAMINATION SUPPORT AND SALES  
hereby certify that annexed is a true copy of the Provisional specification in  
connection with Application No. PP 5831 for a patent by SOLTEC RESEARCH  
PTY LTD and filed on 11 September 1998.



WITNESS my hand this  
Eleventh day of October 1999

KAY WARD  
TEAM LEADER EXAMINATION  
SUPPORT AND SALES

**PRIORITY  
DOCUMENT**

SUBMITTED OR TRANSMITTED IN  
COMPLIANCE WITH RULE 17.1(a) OR (b)

Background

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The present invention provides a new composition for the topical administration of pharmaceutical active ingredients. In particular, the present invention provides aerosol and non-aerosol quick breaking and slow breaking foams for the topical delivery of pharmaceutical active ingredients. In particular, the foam composition is a homogeneous, aqueous alcoholic emulsion system. The foam composition upon actuation produces a stabilised, homogeneous, expandable foam which breaks easily with shear. A composition of this type is often referred to as a "mousse".

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It is known to use mousse compositions to topically deliver pharmaceutical active ingredients. An example of such a composition is in patent application AU80257/87 which discloses a mousse composition for the topical delivery of the pharmaceutical active ingredient, minoxidil.

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However, it would be desirable to provide a mousse composition that enhanced the topical delivery of the pharmaceutical active ingredient while still providing a pharmaceutically elegant and consumer acceptable composition.

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The majority of topical lotions and creams for delivering pharmaceutical active ingredients contain large amounts of petrolatum or some other occlusive agent to act as a barrier over the skin. This barrier reduces the evaporation of moisture from the skin which leads to excess moisture on the skin and in the dermis and enhances the topical delivery of the pharmaceutical active ingredient.

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However, in practice it would not be desirable to include such large amounts of an occlusive agent in a mousse formulation because upon application the occlusive agent would leave a greasy, sticky layer on the skin and is not considered to be acceptable to the consumer.

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In prior art patents US5002680 and US4981677, there is disclosed mousse compositions that contain an occlusive agent such as petrolatum. These compositions are directed towards cosmetic purposes, and provide no disclosure on their suitability to enhance the topical delivery of pharmaceutical active ingredients.

Description of the invention

This invention is predicated on the surprising discovery that a mousse formulation with a low amount of an occlusive agent is still able to enhance the topical delivery of pharmaceutical active ingredients while remaining an elegant and consumer acceptable composition.

- 5 In a first aspect of the invention there is provided a mousse composition which includes at least one pharmaceutical active ingredient to be topically administered, and up to 40% of an occlusive agent.

The mousse base can be made using compositions that are well known in the art.

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The aerosol propellant used in the mousse composition may be any suitable gas, such as propane, butane, CFCs, HFCs, nitrogen or air. In a preferred embodiment the aerosol propellant is a hydrocarbon.

- 15 The mousse composition may include several components, including surfactants, fatty alcohols, fatty acids and salts and the like. In a preferred embodiment the mousse composition includes cetearyl glucoside.

- 20 The occlusion agent may be any active ingredient or combination thereof that provides a hydration barrier to the skin. Examples of suitable occlusion agents include mineral oils and greases, long chain acids, animal fats and greases, vegetable fats and greases, water insoluble polymers and the like.

In a preferred embodiment the occlusion agent is petrolatum.

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The amount of occlusion agent in the mousse composition may be up to 40% based on the total weight of the composition. In a preferred embodiment of the invention the amount of occlusion agent in the mousse composition may be up to 20%.

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- 30 In a more preferred embodiment of the invention the amount of occlusion agent in the mousse composition may be up to 10%.

- 35 Any pharmaceutical active ingredient to be applied topically may be used with the mousse composition of the present invention. In particular, corticosteroids are one class of pharmaceutical active ingredients that may be used with the mousse composition. In a preferred embodiment, the pharmaceutical active ingredient is clobetasol propionate.

## Examples

Non-limiting examples according to the present invention are as follows:

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### Example

Ingredient	1	2	3	4	5	6	7
Petrolatum	10%	10%	10%	20%	10%	10%	10%
Clobetasol Propionate	—	"	"	—	—	"	0.05%
10 Sorbitan Isostearate	0.7%	0.7%	—	"	"	"	—
Ceteth 20	0.3%	0.3%	"	"	—	—	"
Water	84%	83%	82.5%	70%	72.5%	72.3%	72.25%
Hydrocarbon Propellant	5%	5%	5%	5%	5%	5%	5%
Isocetyl alcohol	—	1%	"	—	"	"	—
15 Cetearyl glucoside	"	"	2.5%	5%	2.5%	2.5%	2.5%
Alkyl benzoates	"	"	—	"	10%	10%	10%
Preservative(s)	"	"	—	"	"	0.2%	0.2%

20 Compositions not specifically exemplified or referred to here in above but nevertheless within the ambit of the broad terms of the invention are considered to be implicitly disclosed herein.

Dated this <sup>July</sup> 30<sup>th</sup> day of September 1998

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30 Soltec Research Pty Ltd

09/719662

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## PCT REQUEST

Original (for SUBMISSION) - printed on 08.09.1999 11:36:24 AM

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0	<b>For receiving Office use only</b>	
0-1	International Application No.	
0-2	International Filing Date	
0-3	Name of receiving Office and "PCT International Application"	
0-4	<b>Form - PCT/RO/101 PCT Request</b>	
0-4-1	Prepared using	PCT-EASY Version 2.84 (updated 01.07.1999)
0-5	<b>Petition</b> The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty	
0-6	<b>Receiving Office (specified by the applicant)</b>	Australian Patent Office (RO/AU)
0-7	<b>Applicant's or agent's file reference</b>	40137363
I	<b>Title of invention</b>	MOUSSE COMPOSITION
II	<b>Applicant</b>	
II-1	This person is:	applicant only
II-2	Applicant for	all designated States except US
II-4	Name	FH FAULDING & CO LIMITED
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II-6	State of nationality	AU
II-7	State of residence	AU
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IV-1	<b>Agent or common representative; or address for correspondence</b> The person identified below is hereby/has been appointed to act on behalf of the applicant(s) before the competent International Authorities as:	<b>agent</b>
IV-1-1	Name	<b>FREEHILLS PATENT ATTORNEYS</b>
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IV-1-3	Telephone No.	
IV-1-4	Facsimile No.	
IV-1-5	e-mail	
<b>V</b>	<b>Designation of States</b>	<b>AP: GH GM KE LS MW SD SL SZ UG ZW and any other State which is a Contracting State of the Harare Protocol and of the PCT</b> <b>EA: AM AZ BY KG KZ MD RU TJ TM and any other State which is a Contracting State of the Eurasian Patent Convention and of the PCT</b> <b>EP: AT BE CH&amp;LI CY DE DK ES FI FR GB GR IE IT LU MC NL PT SE and any other State which is a Contracting State of the European Patent Convention and of the PCT</b> <b>OA: BF BJ CF CG CI CM GA GN GW ML MR NE SN TD TG and any other State which is a member State of OAPI and a Contracting State of the PCT</b>
V-1	<b>Regional Patent</b> (other kinds of protection or treatment, if any, are specified between parentheses after the designation(s) concerned)	<b>AE AL AM AT AU AZ BA BB BG BR BY CA</b> <b>CH&amp;LI CN CR CU CZ DE DK DM EE ES FI GB</b> <b>GD GE GH GM HR HU ID IL IN IS JP KE KG</b> <b>KP KR KZ LC LK LR LS LT LU LV MD MG MK</b> <b>MN MW MX NO NZ PL PT RO RU SD SE SG SI</b> <b>SK SL TJ TM TR TT UA UG US UZ VN YU ZA</b> <b>ZW</b>
V-2	<b>National Patent</b> (other kinds of protection or treatment, if any, are specified between parentheses after the designation(s) concerned)	

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V-5	<b>Precautionary Designation Statement</b> In addition to the designations made under items V-1, V-2 and V-3, the applicant also makes under Rule 4.9(b) all designations which would be permitted under the PCT except any designation(s) of the State(s) indicated under item V-6 below. The applicant declares that those additional designations are subject to confirmation and that any designation which is not confirmed before the expiration of 15 months from the priority date is to be regarded as withdrawn by the applicant at the expiration of that time limit.		
V-6	<b>Exclusion(s) from precautionary designations</b>	NONE	
VI-1	<b>Priority claim of earlier national application</b>		
VI-1-1	Filing date	11 September 1998 (11.09.1998)	
VI-1-2	Number	PP5831	
VI-1-3	Country	AU	
VI-2	<b>Priority document request</b> The receiving Office is requested to prepare and transmit to the International Bureau a certified copy of the earlier application(s) identified above as item(s):	VI-1	
VII-1	<b>International Searching Authority Chosen</b>	Australian Patent Office (ISA/AU)	
VIII	<b>Check list</b>	number of sheets	electronic file(s) attached
VIII-1	Request	4	-
VIII-2	Description	12	-
VIII-3	Claims	3	-
VIII-4	Abstract	1	92510053.txt
VIII-5	Drawings	4	-
VIII-7	TOTAL	24	
VIII-8	<b>Accompanying items</b>	paper document(s) attached	electronic file(s) attached
VIII-8	Fee calculation sheet	✓	-
VIII-16	PCT-EASY diskette	-	diskette
VIII-18	<b>Figure of the drawings which should accompany the abstract</b>	1	
VIII-19	<b>Language of filing of the International application</b>	English	
IX-1	<b>Signature of applicant or agent</b>		
IX-1-1	Name	FREEHILLS PATENT ATTORNEYS	
IX-1-2	Name of signatory	JONES, Paul	

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10-1	<b>Date of actual receipt of the purported International application</b>	
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10-2	Drawings:	
10-2-1	Received	
10-2-2	Not received	
10-3	Corrected date of actual receipt due to later but timely received papers or drawings completing the purported international application	
10-4	Date of timely receipt of the required corrections under PCT Article 11(2)	
10-5	International Searching Authority	ISA/AU
10-6	Transmittal of search copy delayed until search fee is paid	

## FOR INTERNATIONAL BUREAU USE ONLY

11-1	Date of receipt of the record copy by the International Bureau	
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